TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Final Rule
LSA Document #18-158(F)

DIGEST

Amends 410 IAC 3-3-3 to update and add to the list of disorders all newborns and infants shall be screened for. Adds 410 IAC 3-3-3.5 to set standards for pulse oximetry screenings. Amends 410 IAC 3-3-5 to include pulse oximetry in laboratory reporting. Amends 410 IAC 3-3-13 to increase the fee charged for newborn screenings to cover the cost of screening for a new disorder. Effective 30 days after filing with the Publisher.

410 IAC 3-3-3; 410 IAC 3-3-3.5; 410 IAC 3-3-5; 410 IAC 3-3-13

SECTION 1. 410 IAC 3-3-3, AS READOPTED AT 20181024-IR-410180328RFA, IS AMENDED TO READ AS FOLLOWS:

410 IAC 3-3-3 Screening for certain disorders; collection procedures

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 3. (a) Except as provided for in section 2(b) of this rule, all newborns and infants born in the state of Indiana shall be screened for the following:

~~(1) Phenylketonuria.~~
~~(2) Hypothyroidism.~~
~~(3) Galactosemia.~~
~~(4) Homocystinuria.~~
~~(5) Maple syrup urine disease.~~
~~(6) Hemoglobinopathies, including sickle cell anemia.~~
~~(7) Congenital adrenal hyperplasia.~~
~~(8) Biotinidase deficiency.~~
~~(9) Cystic fibrosis.~~
~~(10) Hearing impairment.~~
~~(11) Other genetic conditions that are detectable at birth via newborn screening methods, including, but not limited to, the following:~~
~~(A) Tandem mass spectrometry (MS/MS).~~
~~(B) High volume radioimmunoassay.~~
~~(C) Hemoglobin electrophoresis.~~
~~(D) Isoelectric focusing.~~
~~(E) Bacterial inhibition assays.~~
~~(F) Immunoreactive trypsin (IRT).~~
~~(G) DNA testing.~~

(1) The following endocrine disorders:
(A) Congenital adrenal hyperplasia (CAH).
(B) Hypothyroidism.
(2) The following hemoglobinopathies:
(A) Sickle cell anemia Hb SS.
(B) Hb S/C.
(C) Hb S/beta-thalassemia.
(D) Other Hb variant including genetic trait.
(3) The following metabolic conditions:
(A) The following amino acid (AA) disorders (include urea cycle disorders):
(i) Arginase deficiency (argininemia).
(ii) Argininosuccinic aciduria.
(iii) Biopterin cofactor defects.
(iv) Citrullinemia, type I.
(v) Citrullinemia, type II (also called Citron deficiency).
(vi) Homocystinuria (HCY).
(vii) Hypermethioninemia.
(viii) Hyperphenylalaninemia (also called H-Phe).

(ix) Maple syrup urine disease (MSUD).
(x) Phenylketonuria (PKU).
(xi) Tyrosinemia type I.
(xii) Tyrosinemia type II.
(xiii) Tyrosinemia type III.
(B) The following fatty acid oxidation (FAO) disorders:
(i) 2, 4-dienoyl-CoA reductase deficiency.
(ii) Carnitine-Acylcarnitine translocase deficiency (CACT).
(iii) Carnitine palmitoyltransferase deficiency I (CPT IA).
(iv) Carnitine palmitoyltransferase deficiency II (CPT II).
(v) Carnitine uptake defect (CUD).
(vi) Glutaric acidemia type II.
(vii) Long chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD).
(viii) Medium chain acyl-CoA dehydrogenase deficiency (MCAD).
(ix) Medium/short chain L-3-hydroxyacyl-CoA dehydrogenase deficiency (M/SCHAD).
(x) Trifunctional protein deficiency.
(xi) Very long chain acyl-CoA dehydrogenase deficiency (VLCAD).
(xii) Medium-chain ketoacyl-CoA thiolase deficiency (MCAT).
(C) The following organic acidemia (OA):
(i) 2-Methylbutyrylglycinuria (2-MBG).
(ii) 3-Hydroxy-3-methyl glutaric aciduria (HMG).
(iii) 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC deficiency).
(iv) 3-Methylglutaconic acidemia (3-MGA).
(v) Beta-ketothiolase deficiency.
(vi) Glutaric acidemia type I (GA type I).
(vii) Isobutyrylglycinuria (IBG).
(viii) Isovaleric acidemia (IVA).
(ix) Malonic aciduria (MAL).
(x) Methylmalonic acidemia (MUT or methylmalonyl-CoA mutase).
(xi) Methylmalonic acidemia with cobalamin disorders (CblA and CblB).
(xii) Methylmalonic acidemia with homocystinuria (CblC and CblD).
(xiii) Propionic acidemia.
(xiv) 2-Methyl-3-hydroxybutyric aciduria (2M3HBA).
(4) The following other inborn errors of metabolism:
(A) Biotinidase deficiency.
(B) Galactosemia (classic galactosemia or G/G, galactosemia D/G variant and other galactosemia variants).
(5) The following other genetic conditions:
(A) Cystic fibrosis.
(B) Severe combined immunodeficiencies (SCID).
(C) Spinal muscular atrophy (SMA).
(6) Other genetic conditions that are detectable at birth via newborn screening methods, including, but not limited to, the following:
(A) Tandem mass spectrometry.
(B) High performance liquid chromatography.
(C) Isoelectric focusing.
(D) Time resolved fluoroimmunoassay: immunoreactive trypsinogen (IRT) measurement.
(E) Other enzymatic assay.
(F) Fluorometric assay.
(G) DNA mutation analysis.

(b) The responsible physician, midwife, birthing center, or hospital shall collect a specimen of the newborn or infant's blood on a filter paper kit approved by the department. The specimen shall consist of capillary blood obtained by heel puncture and applied directly to the special filter paper. All circles shall be saturated with blood from one (1) side of the filter paper only. All information requested on the form attached to the special filter paper shall be provided. The specimen shall be air dried and then inserted into the protective envelope with complete data. If multiple specimens are forwarded in one (1) envelope, care must be taken to avoid cross-contamination. Completed specimens shall be forwarded to a designated laboratory within twenty-four (24) hours after collection.

(c) The newborn or infant's blood for these tests shall be collected not earlier than ~~forty-eight (48)~~ **twenty-four**

(24) hours after birth ~~and not before the newborn or infant has been on a protein diet for at least twenty-four (24) hours, except as stated in subsection (d),~~ and not later than ~~one hundred twenty (120)~~ **forty-eight (48)** hours after birth, except as stated in ~~subsection~~ **subsections** (f) **and (g).**

(d) When a live birth occurs in a hospital or birthing center, the responsible physician or midwife shall have a specimen of the newborn or infant's blood taken prior to the newborn or infant's discharge from the hospital. If the newborn is discharged from the hospital before ~~forty-eight (48)~~ **twenty-four (24)** hours after birth, ~~or before being on a protein diet for twenty-four (24) hours,~~ a blood specimen shall be collected regardless, but collection shall be repeated after forty-eight (48) hours and not later than one hundred twenty (120) hours after birth. The hospital or birthing center shall provide a written notice to the parents, at or before discharge, of the requirements for the newborn to be tested again prior to one hundred twenty (120) hours after birth.

(e) When a live birth occurs in a facility other than a licensed hospital or birthing center, it shall be the responsibility of the physician or midwife in attendance at the birth to ~~assure~~ **ensure** that the newborn or infant is referred to an appropriate facility, such as a physician office, hospital, birthing center, or local health department, and to make the arrangements to obtain and submit a satisfactory blood specimen in accordance with this section. In the absence of an attending physician or midwife, the registrar of births shall refer the newborn or infant immediately to the parent's physician or to the local health department for submission of a specimen in accordance with this section and notify the MCH/NBS immediately.

(f) For preterm **or low birth weight (less than two thousand (2,000) grams)** newborns or infants, the **initial** specimen shall be taken ~~on the day of discharge or on the sixth day if nursery stay is prolonged beyond six (6) days.~~ **not earlier than twenty-four (24) hours after birth and not later than forty-eight (48) hours after birth. A repeat specimen collection shall be taken not earlier than fourteen (14) days and not later than thirty (30) days after birth or the day of discharge, whichever comes first.** Prematurity and transfusion status shall be noted on the request form in the space provided. If the newborn or infant is to receive ~~total exchange~~ transfusion, then the specimen for the newborn screening test is to be obtained ~~from the first draw,~~ **prior to transfusion,** which represents the newborn or infant's own blood. **If the pre-transfusion collection occurred before twenty-four (24) hours after birth, a repeat collection shall be taken not earlier than twenty-four (24) hours post-transfusion start time. Additional repeat collection shall be taken at fourteen (14) days and thirty (30) days or day of discharge, whichever comes first.**

(g) **Except** for newborns ~~or~~ **and** infants **described in subsection (f), for newborns or infants** within the neonatal intensive care unit (NICU), the ~~responsible physician or hospital shall follow the routine NICU rescreening guidelines and collect specimens as specified by the department.~~ **initial collections shall be taken not earlier than twenty-four (24) hours after birth and not later than forty-eight (48) hours after birth. A repeat collection shall be taken at fourteen (14) days and thirty (30) days or day of discharge, whichever comes first.**

(Indiana State Department of Health; 410 IAC 3-3-3; filed Nov 7, 1986, 3:30 p.m.: 10 IR 416; filed Sep 17, 1999, 10:42 a.m.: 23 IR 324; errata filed Nov 19, 1999, 9:31 a.m.: 23 IR 814; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)

SECTION 2. 410 IAC 3-3-3.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 3-3-3.5 Pulse oximetry measurement for critical congenital heart disease

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 3.5. (a) Except as provided for in section 2(b) of this rule, every newborn shall be given a pulse oximetry screening examination:
(1) not earlier than twenty-four (24); and
(2) not later than forty-eight (48);
hours after birth. Preterm newborns or infants shall be given a pulse oximetry screening, including repeat screenings, at or near the time the specimen is taken as provided for in section 3(f) of this rule.

(b) Pulse oximetry screenings shall be taken from pulse oximetry readings on the right hand and one (1) foot.

(c) A passing pulse oximetry reading is an initial reading or repeat readings, which is:
(1) greater than or equal to ninety-five percent (95%) on the right hand or foot; and
(2) less than or equal to three percent (3%) variance between the right hand and foot.

(d) Except as provided in subsection (e), newborns who do not pass the initial pulse oximetry reading as described in subsection (c) shall have up to three (3) repeat readings performed at one (1) hour increments. If the newborn does not pass one (1) three (3) repeat readings as described in subsection (c), the newborn shall be immediately referred for cardiology evaluation.

(e) Newborns with an initial pulse oximetry reading of less than ninety percent (90%) on right hand or foot shall be immediately referred for cardiology evaluation.

(f) Newborns referred for cardiology evaluation as required in either subsection (d) or (e) shall be given, at a minimum, diagnostic testing via echocardiogram.

(Indiana State Department of Health; 410 IAC 3-3-3.5; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)

SECTION 3. 410 IAC 3-3-5, AS READOPTED AT 20181024-IR-410180328RFA, IS AMENDED TO READ AS FOLLOWS:

410 IAC 3-3-5 Laboratory reports

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 5. Specific reporting/follow-up requirements vary based on whether the analysis indicated whether the specimen met all requirements for a valid screening test and whether the screening results were normal, unsatisfactory, abnormal, presumptive positive, or confirmed positive. The laboratory shall report as follows:

(1) Negative test results shall be reported within seven (7) days of the date of receipt of the specimen to the following:
  (A) MCH/NBS.
  (B) The hospital or birthing center submitting the specimens.
  (C) The responsible physician or midwife.
The report of the test results shall become part of the patient's clinical record.

(2) Presumptive positive tests shall be reported immediately by telephone to the hospital, birthing center, responsible physician, midwife, or collection source. The notification shall be recorded in the laboratory's records, specifying date and time of notification, person notified, and information provided. This shall be followed by an official report within three (3) days. The report of the test result shall become part of the patient's clinical record. If there is no known responsible physician or midwife, the appropriate state-contracted newborn screening follow-up specialist shall be notified.

(3) Confirmed positive tests shall be reported immediately by telephone to the hospital, birthing center, responsible physician, or midwife and MCH/NBS. The notification shall be recorded in the laboratory's records specifying date and time of notification, person notified, and information provided. This shall be followed by an official report within three (3) days. The report of the test result shall become part of the patient's clinical record. If there is no known responsible physician or midwife, the local health officer in the county of the mother's residence shall be notified.

(4) Unsatisfactory specimens shall be reported immediately by telephone to the hospital or birthing center and responsible physician, midwife, or other health care provider submitting the specimen with an explanation about the reason for rejection. In the event that the responsible physician, midwife, or health care provider who submitted the specimen is no longer the primary health care provider, he or she shall be responsible for notifying the current primary health care provider.

(5) In the event a specimen is rejected for any reason as unsatisfactory, the health care provider responsible for the newborn or infant's care at the time of the report shall be responsible for the submission of an acceptable specimen within forty-eight (48) business hours. If the laboratory does not receive the repeat specimen within five (5) days, it shall send the collection source and responsible health care provider

notification of the requirement for a repeat screen, with a copy provided for MCH/NBS. A reminder will be sent five (5) business days after the initial notification if no repeat specimen has been received. The laboratory will notify MCH/NBS immediately by telephone if no repeat specimen has been received seven (7) to ten (10) business days after the reminder letter has been sent so that public health nurse assistance can be obtained.
(6) The designated laboratories performing the tests shall maintain records of the results of all screening and follow-up testing of newborns or infants for these conditions in accordance with Indiana requirements for records management.
(7) The laboratory shall provide newborn heel-stick, **pulse oximetry,** and hearing screening reports to the department in the format, media, and time frame specified by the department.

(Indiana State Department of Health; 410 IAC 3-3-5; filed Nov 7, 1986, 3:30 p.m.: 10 IR 417; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)

SECTION 4. 410 IAC 3-3-13, AS READOPTED AT 20181024-IR-410180328RFA, IS AMENDED TO READ AS FOLLOWS:

410 IAC 3-3-13 Newborn screening fund; fees; disposition; reporting requirements

Authority: IC 16-19-3-4; IC 16-41-17-9; IC 16-41-17-10
Affected: IC 16-41-17

Sec. 13. (a) The program involving the department and MCH/NBS as described in this rule shall be funded by the collection of a newborn screening fee for each initial newborn screening performed. The designated laboratory shall assess and collect the full amount of the newborn screening fee from hospitals, birthing centers, public health nurses, physicians, and midwives submitting newborn screening specimens. No surcharge will be assessed, collected, or reported for newborns or infants receiving repeat screens. The accumulated collections from the newborn screening fees shall be submitted on a monthly basis by the designated laboratory to the division of finance at the department. Payments shall be postmarked not later than five (5) days after the close of the preceding month. The designated laboratory shall also submit a monthly report on the number of newborns screened. Revenues submitted by the laboratory shall correspond with the number of newborns screened.

(b) The newborn screening fee shall be ~~thirty~~ **one hundred** dollars ~~($30)~~ **($100)** based on the projected cost of the program described in this rule and the estimated number of newborns per year. The fees shall be deposited in the newborn screening fund. Funds for the program described in this rule shall be disbursed by the department in accordance with normal procedures prescribed by the state budget agency and the state board of accounts. The fee shall be reviewed annually by the department.

(Indiana State Department of Health; 410 IAC 3-3-13; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)

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